AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,039	08/28/2003	Ronald J. Pettis	11219-060-999	6947

20583 7590 01/17/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,039	PETTIS, RONALD J.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) *1-21,37,39 and 41-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-36,38 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 15 December 2005. Applicant elects Group III, claims 22-40, with traverse.

The traversal is on the grounds that since the claims of Groups I - IV are all classified in the same class and subclass, the prior art pertinent to one group will also be relevant to the other groups. Thus, the search and examination of the claims of Groups I - IV would not be a serious burden on the Examiner.

Applicant's traversal is unpersuasive. While a search of the prior art for one group may overlap with that of another group, the searches are not co-extensive and thus would be an undue burden on Office resources even if the Groups were arbitrarily placed in the same class and subclass. The PTO classification is merely an administrative convenience and is not dispositive of relatedness of applications.

The restriction among the different methods is maintained.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that there are two claims 38 in this application. For examination purposes, the second claim 38 has been treated as if it were claim 39. Claim 40 is presumed to depend from the first claim 38. Appropriate correction is required.

Claims 1-90 are pending. Claims 1-21, 37, 39, and 41-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected

invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 15 December 2005.

Claims 22-36, 38, and 40 are examined in the instant application and read to the elected species, α interferon.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed on 20 May 2004, is attached to the instant Office action.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is a mere repetition of the title and does not include what is new in the art to the invention pertains. Correction is required. See MPEP § 608.01(b).

Double patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 22-35 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 28-41 of copending Application No. 10/487,485. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-24, 26, and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, and 29 of copending Application No. 09/606,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that are recited in the copending claims, that is, claims 2, 4, and 29 of the copending application fall entirely within the scope of the instant claims 22-24, 26, and 31 or, in other words, claim 22-24, 26, and 31 are anticipated by claims 2, 4, and 29 of the application serial No. 09/606,909.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

because

Case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim. *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-28 and 30-35 are rejected under 35 U.S.C. §102(b) as being anticipated by Zahn *et al.* (2000).

The instant claims are directed to a method of administering an immunomodulatory substance comprising injecting or infusing the substance intradermally through one or more micro needles having a length and outlet suitable for selectively delivering the substance into the dermis to obtain absorption of the substance in the dermis, wherein absorption of the substance in the dermis produces improved systemic pharmacokinetics, i.e. increased bioavailability, decreased T_{max}, increased C_{max}, decreased T_{lag}, and enhanced absorption rate, and wherein the

microneedle is 30 gauge or narrower, has an outlet of from 0 to 1 mm, and is configured in a delivery device which positions the microneedle perpendicular to skin surface.

Zahn *et al.* teach a method of short-term intradermal drug delivery (see abstract) through an array of micro needles (page 295, right column, line 3) with an outer height of 0.1 mm (page 298, right column, line 13), which can handle 90° bends (page 295, right column, line 17). The size of the array is at least five by five. Each microneedle is much narrower than a 20 gauge needle. See figure 1. This method increases the flow capacity (abstract), which in turn enhances absorption rate and increases the drug bioavailability, which is inherently manifested in a decreased T_{max}, an increased C_{max}, a decreased T_{lag}.

Thus, the instant invention is anticipated by Zahn *et al.*

Claims 22-28, 31, and 33-35 are rejected under 35 U.S.C. §102(b) as being anticipated by Henry *et al.* (1998).

The instant invention is summarized as above.

Henry *et al.* teach a method of drug delivery through a 20x20 array of microneedles (page 923, Definition and Deposition of Mask) to increase transdermal transport rates (page 922, Introduction, second paragraph). This method increases permeability of human skin *in vitro* to a model drug (abstract), which would result in the increase of the drug absorption rate and bioavailability, which is inherently manifested in a decreased T_{max}, an increased C_{max}, a decreased T_{lag}. The microneedles are approximately 0.15 mm in length (page 922, right column, last sentence), which is long

enough to cross the permeability barrier but not so long that they stimulate nerves, thereby potentially causing no pain in humans.

Thus, the instant invention is anticipated by Henry *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22, 36, 38, and 40 are rejected under 35 U.S.C. §103(a) as being unpatentable over Henry *et al.* (1998) in view of Sato *et al.* (1996).

The instant invention is further limited to administering α interferon. The relevance of Henry *et al.* is set forth above.

Henry *et al.* do not teach the α interferon specifically but point out the substances to be delivered, such as protein-based, DNA-based, and other therapeutic compounds (page 922, Introduction, first paragraph), which reads on α interferon.

Sato *et al.* teach the method of intradermal injection of genes expressing immunostimulatory proteins such as α interferon. See page 352, right column, last paragrah.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the Henry method of drug delivery through micro needles to the administration of α interferon to enhance the delivery across skin. One

skilled in the art would have been motivated to combine the Henry method with the Sato drug ingredient into the claimed invention with a reasonable expectation of success because Henry *et al.* demonstrate an improvement in the absorption of the substance in the skin.

Thus, claims 22, 36, 38, and 40 are obvious over Henry *et al.* in view of Sato *et al.*

Claims 22, 29, 36, 38, and 40 are rejected under 35 U.S.C. §103(a) as being unpatentable over Zahn *et al.* (2000) in view of Sato *et al.* (1996).

The instant invention is further limited to using micro needles that are from about 0.5 mm to about 1.7 mm long. The relevance of Zahn *et al.* is set forth above.

Zahn *et al.* do not teach the length of micro needles to be from about 0.5 mm to about 1.7 mm, but states that since the shape of a micro needle is defined lithographically micro needles can be any size. See Introduction, first paragraph.

Zahn *et al.* do not teach the α interferon specifically but point out the substances to be delivered, such as drug, cell, or cellular based vaccine (abstract), which reads on α interferon.

Sato *et al.* teach the method of intradermal injection of genes expressing immunostimulatory proteins such as α interferon.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the Zahn method of drug delivery through micro needles to the administration of α interferon. One skilled in the art would have been

motivated to combine the Zahn method with the Sato ingredient into the claimed invention and modify the length of the micro needle to reach the desired depth of skin puncture with a reasonable expectation of success because Zahn *et al.* demonstrate how to make the micro needle and teach how to improve the absorption of the substance in the dermis and ultimately improve the systemic pharmacokinetics.

Thus, claims 22, 29, 36, 38, and 40 are obvious over Zahn *et al.* in view of Sato *et al.*

Remarks

No claim is allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
Patent Examiner
10 January 2006

JEFFREY STUCKER
PRIMARY EXAMINER